EXHIBIT 11

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. Undetermined quantities of all articles of finished and in-process foods, etc. Defendants, and HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT, Claimants.	Civil Action No. 1:13-cv-3675 Hon. Willis B. Hunt, Jr.
HI-TECH PHARMACEUTICALS, INC., Plaintiff, v. MARGARET A. HAMBURG, M.D., et al. Defendants.	

HI-TECH PHARMACEUTICALS, INC., AND JARED WHEAT'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT DISMISSING THE SEIZURE ACTION OF THE UNITED STATES AND GRANTING JUDGMENT ON CLAIMANTS' ADMINISTRATIVE PROCEDURE ACT COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

INTRODUCTION

Since November of 2013, millions of dollars' worth of goods owned by Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), and Jared Wheat (hereinafter "Claimants") have sat in Hi-Tech's Georgia facilities losing their potency and fast expiring so that they are no longer saleable or useable. This is the direct result of the United States' (hereinafter the "Government") false contention that the raw ingredient 1,3 Dimethylamylamine HCL or DMAA[1] is an unsafe, unapproved food additive. The Government's contention is both factually and legally incorrect. Accordingly, the Government's seizure action should be dismissed, the detention order against Claimants' goods should be lifted, and summary judgment should be entered as to Claimants' Administrative Procedure Act Complaint.

As demonstrated herein, DMAA is a constituent or extract of the geranium plant. Multiple researchers conducting separate studies have repeatedly detected DMAA in geraniums. Because DMAA can be found naturally in geraniums, it is a "dietary ingredient," not a "food additive," and is not subject to seizure as such by the Government. All of the detained goods that contain DMAA should therefore be immediately released.

---

[1] DMAA has multiple synonyms and acronyms. For example, "MHA" is the abbreviated form of Methylhexanamine, another name for DMAA. Other documents refer to it as "DMP." For simplicity's sake, regardless of how it's referred to in supporting documents, we will use the acronym DMAA in this brief.

Most importantly, whether characterized as a dietary ingredient or food additive, the overwhelming evidence in the record in this litigation is that DMAA is safe for human consumption as recommended by Hi-Tech's product labels. Hi-Tech has presented numerous experts on this point, including a board certified neurologist, a family practice doctor, a pharmacologist/physician and a prominent toxicologist. The Government has presented zero evidence on safety, and therefore the point is undisputed.

The Government's efforts to classify DMAA as a food additive rather than a dietary ingredient are motivated by a desire to avoid the requirements of the Dietary Supplement Health and Education Act ("DSHEA"), which places the burden on the Government to prove that a dietary ingredient is unsafe and imposes other prerequisites before the Government can take action to ban or seize a dietary ingredient. Sadly, the Government has lost its way in this matter. Not only has the Government misinterpreted the law in this case, as demonstrated herein, it has been involved in a wide ranging scheme wherein supposedly independent scientists concealed and manipulated published research to suppress information that DMAA was indeed present in geraniums. In essence, millions of taxpayer dollars have been expended to perpetuate a scientific fraud, which has been compounded by the Government's complicity and behavior during discovery.

To reiterate, DMAA is a safe and lawful dietary ingredient. Moreover, even if it were not a dietary ingredient, its undisputed record of safety renders it Generally Recognized as Safe ("GRAS"), a classification that also exempts it from the statutory requirements set for food additives. The Government does not have a proper legal basis to detain and seize Claimants' property. Additionally, the Government's conduct in funneling millions of dollars to researchers that committed scientific fraud renders it liable to the Claimants under the Administrative Procedure Act and Due Process. The Court should order relief appropriate to remedy these injustices.

STATEMENT OF MATERIAL FACTS

DMAA is an "organic substance," Declaration of Jack Wenik ("Wenik Decl.") Ex. 1, Declaration of Cara Welch ("Welch Decl.") at ¶ 17, which is found in the geranium plant. Hi-Tech, is a Georgia corporation that manufactures and distributes dietary supplements that are sold in more than 100,000 retail locations including, for example, GNC, CVS, Walgreen's, Wal-Mart, K-Mart, Kroger, and convenience stores nationwide. Wenik Decl., Ex. 66, Claimants' Administrative Procedure Act Complaint; Answer of United States, Doc. 52 at ¶ 5. Hi-Tech incorporates DMAA into many of the dietary supplements it manufactures and sells including, for example, Black Widow, Lipodrene, Yellow Scorpion, Fastin XR, and Stimerex-ES. *Id*. Since 2010, Hi-Tech has sold over 200 million doses of

DMAA containing products with only a handful of adverse events of any sort. Wenik Decl., Ex. 2, Declaration of Michael Lumpkin, Ph.D., DABT ("Lumpkin Decl.") at ¶¶ 98-99. The Government has detained large quantities of Hi-Tech's DMAA containing goods, which, to this day, remain impounded at Hi-Tech facilities in Georgia. Wenik Decl., Ex. 3, United States' Responses to Requests for Admission at Requests 12 and 13.

The saga of the Government's war against DMAA begins sometime in 2010. Somewhere in that time frame, Amy Eichner, an official of the United States Anti-Doping Agency ("USADA"), with virtually no training or expertise in chemistry, Wenik Decl., Ex. 4, Deposition of Amy Eichner ("Eichner Dep.") at 12:9-12:22, became convinced that DMAA presented a health risk to athletes, Wenik Decl., Ex. 4-5, Eichner Dep. at 27:6-28:Ex.19; Deposition of Daniel Fabricant ("Fabricant Dep.) at 52:2-53:21, and that it could not be found in the geranium plant, but was rather a "drug." *See, e.g.*, Wenik Decl., Ex. 6, November 2010 email correspondence between Amy Eichner and Robert Moore, stamped GOV-007409. No doubt she was also influenced at some later point by the wide spread publicity surrounding the death of serviceman Michael Lee Sparling, who died during military training on June 1, 2011, a death that news media suggested was caused by DMAA. *See, e.g.*, Wenik Decl., Ex. 7, March 17, 2013 email correspondence between Daniel Fabricant, Brian Somers, and Corey Hilmas, stamped GOV-

008127 through GOV-008138. Eichner spoke to Sparling's family, which had filed a wrongful death suit as a result of the incident. Wenik Decl., Ex. 4, Eichner Dep. at 39:15-40:17.

Eichner took her concerns to the Food and Drug Administration ("FDA"). On October 13, 2010, Dr. Robert J. Moore, an FDA supervisor in the Division of Dietary Supplements, advised Eichner that DMAA "is found in many plants," that plants are dietary ingredients under DSHEA, and that DMAA "appears to be a dietary ingredient under [DSHEA] because it is a constituent of another dietary ingredient (i.e., a plant)." Wenik Decl., Ex. 8, October 2010 through April 2011 email correspondence between Amy Eichner, Robert Moore, and Daniel Fabricant regarding the presence of DMAA in geranium, stamped GOV-007430 through GOV-007435. Later that same day, Dr. Moore advised Eichner that DMAA could be found in geranium oil which had "a fairly long history of food use as an essential oil" and also provided her the cite to a 1996 scientific study by Ping that had detected DMAA in geranium oil. *Id.* at 007430-007431.

Eichner was dissatisfied with Dr. Moore's response. In her view, the Ping study was from a "third rate university in China" and DMAA was a drug. Wenik Decl., Ex. 9, October 2010 through December 2010 correspondence among Amy Eichner, FDA representatives and National Science Foundation representatives regarding the presence of DMAA in geranium, stamped USADA007072 through

USADA007077, at 007073. Eichner enlisted the aid of the National Center for Natural Product Research at the University of Mississippi ("NCNPR") to conduct research regarding DMAA. Her main contact at this entity was Dr. Ikhlas Khan. Dr. Khan was a professor at the University of Mississippi and the Associate Director of the NCNPR at the University. From October 2002 until January 2015, he was the Center's Assistant Director. Wenik Decl., Ex. 10, Khan Initial Expert Report/Declaration at ¶ 7. Eichner reached out to Dr. Khan, asking him for assistance in determining whether DMAA could be found in geraniums. Wenik Decl., Ex. 11, Deposition of Ikhlas Khan ("Khan Dep.") at 71:5-71:12; Ex. 4, Eichner Dep. at 33:11-33:22. Eichner believed that Dr. Khan would conduct the "definitive" study as to whether DMAA could be found in geraniums. Wenik Decl., Ex. 9, email chain, USADA007072-USADA007077, at USADA007073. Dr. Khan admitted that it was Eichner and her colleague at the USADA, Larry Bowers, who helped form the hypothesis in his first study that DMAA could not be found in geraniums. Wenik Decl., Ex. 11, Khan Dep. at 69:14-70:5.

Eichner was introduced to Dr. Khan's colleague, Dr. Mahmoud A. ElSohly. Wenik Decl., Ex. 4, Eichner Dep. at 33:11-33:22. Dr. ElSohly was also a professor at the University of Mississippi and affiliated with the NCNPR.[2] Additionally, Dr.

[2] As discussed in Point III infra, the NCNPR receives millions in funding from the FDA. The FDA directs and controls the research activities of the NCNPR.

Khan was President of a related entity, Phytochemical Services, Inc., in Mississippi, which performed testing services for NCNPR. Beginning in December 2010, Eichner negotiated with Drs. Khan and ElSohly for them to conduct a study of DMAA and geraniums. Wenik Decl., Ex. 4, Eichner Dep. at 85:11-86:1. In April of 2011, Eichner arranged for a consulting agreement to be executed between the USADA and Dr. ElSohly's company wherein his company would test geranium samples for the presence of DMAA. *See* Wenik Decl., Ex. 12, April 2011 email correspondence between Amy Eichner and Mahmoud ElSohly, Ph.D., stamped ElSohly 3480-3489.

Things did not go as Eichner had planned. On May 27, 2011, she told Drs. Khan and ElSohly that she had heard a rumor that other researchers had detected DMAA in geranium oil and she was concerned how this might affect their efforts to lobby FDA regarding DMAA. Dr. ElSohly responded by informing Eichner that he and his colleagues had developed a very sensitive method to detect DMAA and that they had indeed found low levels of DMAA in the geranium samples that Eichner had supplied to them. Wenik Decl., Ex. 13, May 2011 email correspondence among Amy Eichner, Dr. ElSohly, and Dr. Khan regarding Dr. ElSohly's detection of DMAA in geranium, stamped ElSohly 4318-4322, at 44319. Undaunted, Eichner and her colleague at the USADA, Larry Bowers, agreed with Drs. ElSohly and Khan that the issue could be avoided by simply raising the

detection limit in the published article so that a finding that no DMAA was detected could be reported. *See* Wenik Decl., Ex. 14, June 2011 email correspondence among Amy Eichner, Dr. ElSohly, Dr. Khan, and Larry Bowers regarding Dr. ElSohly's detection of DMAA in geranium, stamped ElSohly 4330-4335. The published article of Drs. Khan and ElSohly, *Pelargonium Oil and Methyl Hexaneamine (MHA): Analytical Approaches Supporting the Absence of MHA in Authenticated Pelargonium graveolens Plant Material and Oil*, Journal of Analytical Toxicology (2012), Wenik Decl., Ex. 15, GOV-027840-GOV-027854, indeed reported that DMAA had not been detected in the geranium samples studied.

It appears that Eichner had a hand in having other test results that showed DMAA to be contained in geraniums suppressed from public view. A team at the University of Texas, including Ying Zhang and Daniel Armstrong, was also looking at the question of whether DMAA was in geraniums in the spring of 2012. Somehow Eichner gained access to an unpublished version of Zhang and Armstrong's results and she forwarded it to Drs. Khan and ElSohly. Wenik Decl., Ex. 16, May 2012 correspondence among Amy Eichner, Dr. ElSohly, and Dr. Khan containing an unpublished version of "1,3-Dimethylamylamine (DMAA) in supplements and geranium plants/products: natural or synthetic?", a 2012 DMAA study by Ying Zhang and Daniel Armstrong, stamped ElSohly 2181-2190. Eichner

admitted the "possibility" that either she or a colleague at the USADA had communicated with the study's authors about this "embargoed" draft to "try and understand" it. Wenik Decl., Ex. 4, Eichner Dep. at 147:13-149:14. The version of the Zhang/Armstrong article of 2012 that Eichner reviewed reported the detection of DMAA in significant amounts in two of eight geranium samples. Wenik Decl., Ex. 17, the unpublished version of "1,3-Dimethylamylamine (DMAA) in supplements and geranium plants/products: natural or synthetic?", a 2012 DMAA study by Ying Zhang and Daniel Armstrong, stamped ElSohly 1738-1743. However, once in the hands of Drs. Khan and ElSohly, the published version reported no detection of DMAA. *See* Wenik Decl., Ex. 18, the published version of "1,3-Dimethylamylamine (DMAA) in supplements and geranium plants/products: natural or synthetic?", a 2012 DMAA study by Ying Zhang and Daniel Armstrong, stamped ElSohly 2600-2604.

Eichner's wish for Government action against DMAA was fulfilled. In April 2012, the FDA sent Warning Letters to several companies that marketed DMAA containing products, advising them that DMAA was dangerous and not a dietary ingredient under DSHEA. Wenik Decl., Ex. 19, April 27, 2012 Press Release. Later the FDA trumpeted its success by noting that all but one of the companies that had received a warning letter had removed DMAA from their products and the marketplace. Wenik Decl., Ex. 20, FDA Consumer Alert entitled

"Stimulant Potentially Dangerous to Health, FDA Warns," which was Exhibit 28 to the Deposition of Dr. Fabricant, at 2. The one holdout, USP Labs, LLC, ultimately caved to FDA pressure and removed DMAA from its products in April 2013, a result that FDA official Dr. Daniel Fabricant happily shared with Dr. Khan. Wenik Decl., Ex. 21, April 2013 email correspondence among Daniel Fabricant, Dr. ElSohly, and Dr. Khan containing the USP Labs, LLC press release announcing the phase-out of its products containing DMAA, stamped Ole Miss 008982-008983.

But all did not go smoothly in the Government's war against DMAA. In August of 2012, an article was published in *Analytical Chemistry Insights* by Charlie Li, which found that DMAA was in geraniums. Wenik Decl., Ex. 22, J.S. Li, M. Chen, and Z.C. Li, Identification and Quantification of Dimethylamylamine in Geranium by Liquid Chromatography Tandem Mass Spectrometry, Analytical Chemistry Insights 2012:7 47-58, stamped GOV-012486 through GOV-012497. This prompted Dr. Khan to reach out to NCNPR's federal program officer, Dr. Daniel Fabricant of the FDA. Dr. Khan proposed to Dr. Fabricant a strategy for a new, multi-center DMAA study to refute the findings of Li's work. Wenik Decl., Ex. 23, August 9, 2012 correspondence between Daniel Fabricant and Dr. Khan regarding a proposed strategy for multi-center research, stamped Ole Miss 009544-009545. Dr. Fabricant approved the strategy. Wenik Decl., Ex. 24, August 9,

2012 correspondence from Daniel Fabricant to Dr. Khan approving the multi-center research, stamped Ole Miss 009560-009561. Thereafter, Drs. Khan and ElSohly began what would become their 2014 Multi-Center Study regarding DMAA and geraniums. *See* Wenik Decl., Ex. 25, *Methylhexanamine is not detectable in Pelargonium or geranium species and their essential oils: A multi-center investigation*," Drug Testing and Analysis (2014), 7(7), 645-54 (the "Multi-Center Study").

Unfortunately for Drs. Khan and ElSohly, the facts did not conform to their belief that DMAA could not be found in geraniums. One of the four laboratories working on the Multi-Center Study reported to Drs. Khan and ElSohly in April 2013 that it had indeed detected DMAA in several geranium samples from China. Wenik Decl., Ex. 26, email correspondence from Min Yang of the Shanghai Institute of Materia Medica notifying Dr. Khan of the detection of DMAA in geranium the Multi-Center Study, stamped ElSohly 2267-2272. Having established previous experience in such matters, Drs. Khan and ElSohly employed their usual technique for ignoring test results inconsistent with their theories by simply raising the detection limit after the fact and ignoring positive DMAA test results. Just a few days later, in April 2013, Dr. ElSohly gave a PowerPoint presentation at the 13th Annual Oxford International Conference on the Science of Botanicals at the University of Mississippi, wherein he suppressed any mention of the positive

DMAA test results. Wenik Decl., Ex. 27, 2013 ElSohly PowerPoint Slides. The PowerPoint slides were shared with Dr. Fabricant who had attended the presentation. Wenik Decl., Ex. 5, Fabricant Dep., at 175:7-175:24; 176:8-177:3; 177:25-178:6. Of course, like the prior DMAA positive test results, the positive DMAA test results from the Multi-Center Study did not make their way into the article published by Drs. Khan and ElSohly. *See* Wenik Decl., Ex. 25, Multi-Center Study. Despite the fact that the FDA funded and directed research that confirmed that DMAA was found in geraniums, at no time did the FDA revise its website or Q&As regarding DMAA to advise the public of these findings. *See* DMAA in Dietary Supplements – Questions & Answers, available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm346576.htm.

In early November 2013, the *Atlanta Journal Constitution* published a lengthy article that discussed Claimants' sale of products containing DMAA. Wenik Decl., Ex. 28, November 2, 2013 *Atlanta Journal Constitution* article. In the article, reporter Danny Robbins related comments by FDA's Dr. Fabricant that the FDA was not aware that Claimants were marketing DMAA-containing products until being informed about this by the *Atlanta Journal Constitution.* The detention of Claimants' products and the Government's seizure action followed shortly after publication of the *Atlanta Journal Constitution* article.

LEGAL ARGUMENT AND SUPPORTING AUTHORITIES

The Legal Standard for Summary Judgment

Summary judgment is appropriate when the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Fed. R. Civ. P.* 56(a). "By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby*, 477 U.S. 242, 247-48 (1986) (emphasis added). Moreover, "a mere scintilla of evidence in support of the nonmoving party will not suffice to overcome a motion for summary judgment." *Young v. City of Palm Bay*, 358 F.3d 859, 860 (11th Cir. 2004).

Thus, "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, 477 U.S. at 248 (citing 10A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2725, pp. 93-95 (1983)). Indeed, summary judgment is mandated when the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322

(1986). Thus, "'discredited testimony is not [normally] considered a sufficient basis for drawing a contrary conclusion.' Instead, the [non-moving party] must present affirmative evidence in order to defeat a properly supported motion for summary judgment." *Anderson*, 477 U.S. at 256-57 (quoting *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 512 (1984)). Similarly, "[s]peculation does not create a *genuine* issue of fact; instead, it creates a false issue, the demolition of which is a primary goal of summary judgment." *Cordoba v. Dillard's Inc.*, 419 F.3d 1169, 1181 (11th Cir. 2005) (citation and quotations omitted); *see also Eubanks v. Henry Cnty.*, 626 Fed. Appx. 250, 253 (11th Cir. 2015) (holding that "[c]onclusory allegations and speculation are insufficient to create a genuine issue of material fact" at the summary judgment stage).

I. The Products Currently Detained by the United States Are Dietary Supplements and/or Dietary Ingredients That Are Safe and Unadulterated and the Government's Seizure Action Should Thus Be Dismissed.

Since the inception of this litigation, substantial quantities of Hi-Tech goods remain impounded at its facilities unsold and unused.[3] Much of the product in

[3] Due to the Government's litigation tactics of obfuscation and delay, substantial quantities of these goods have now exceeded their expiration dates, rendering them unsaleable and/or unusable by Claimants. *See, e.g.*, Wenik Decl., Exs. 29-33, GOV-000621, GOV-000623, GOV-000762, GOV-000791, GOV-000799. There has thus been a de facto "forfeiture" of Claimants' property without the benefit of a proper hearing on the merits. In its Answer to Claimants' Administrative Procedure Act Complaint, the United States admitted that the value of the goods

question is finished goods sold under various brand names such as Fastin, Stimerex-ES, Yellow Scorpion, and other names. Other items consist of raw materials/ingredients used by Hi-Tech to produce dietary supplements. The common theme is that the impounded goods contain DMAA.[4] As set forth below, DMAA is a safe dietary ingredient and the United States has not and cannot meet its burden of proof to maintain its seizure and forfeiture of these goods.

A. The Legal Framework for Regulating Dietary Supplements/Ingredients.

Prior to the enactment of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), the FDA promulgated detailed regulations requiring approval of dietary supplements and their labels by the FDA. *See* 21 C.F.R. §§ 101.13-14; 101.70. The process resembled the pre-market approval process for drugs under the Food, Drug and Cosmetic Act ("FDCA"), which prohibits the sale or marketing of any drug until the FDA deems it safe and effective. *See* 21 U.S.C. § 355. The bar to such approval is high. Safety and effectiveness must normally be shown

---

detained exceeded $2 million. Answer (Doc. 52) at ¶ 2. Claimants reserve their rights to seek compensation and other relief from the Government for their property losses in this matter.

[4] The United States alleges at ¶¶ 22-24 of its Amended Complaint (Doc. 25), that a small portion of the impounded goods purport to contain DMAA but, in fact, do not have DMAA. Claimants address these contentions in Point IV, infra.

through two adequately designed, well-controlled, double-blind clinical trials. *See* 21 C.F.R. § 314.126.

In 1994, however, Congress through DSHEA "narrow[ed] the reach of the FDA's preauthorization scheme" out of concern that "excessive regulation" could shut down the supplement industry, eliminating thousands of well-paying jobs and preventing consumers from accessing safe and beneficial products. *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 224 (2d Cir. 1998) (internal quotation marks omitted). Under DSHEA, so long as the supplement does not contain a "new dietary ingredient" – i.e., an ingredient that was not marketed before the October 15, 1994 effective date of DSHEA – a dietary supplement is considered a "food" and thus the manufacturer is not required to submit evidence proving the product's safety or effectiveness before marketing or selling the product. *See* 21 U.S.C. § 350b(a). A supplement containing such a pre-existing ingredient is presumed safe, and the burden rests with the FDA to prove that the product is an unsafe "[a]dulterated food." 21 U.S.C. § 342(f)(1). Specifically, the Government must show that the dietary supplement or ingredient "presents a significant or unreasonable risk of illness or injury under [its] conditions of use recommended or suggested in labeling…" 21 U.S.C. § 342(f)(1)(A).

Dietary supplements are defined by DSHEA as a product (other than tobacco) which contains one or more "dietary ingredients." A "dietary ingredient"

is defined as either a: vitamin, mineral, herb or other botanical, amino acid, a dietary substance used to supplement the diet by increasing the total dietary intake, or a constituent, abstract or combination of any of the foregoing. *See* 21 U.S.C. § 321(ff). DMAA qualifies as a dietary ingredient by virtue of its being a constituent and/or extract of a botanical, i.e., geraniums.

The Government largely agrees with the above recitation of the statutory framework for regulating dietary supplements/ingredients. Both of the Government's regulatory experts, Dr. Dennis M. Keefe and Dr. Cara R. Welch, cite to several of the statutes discussed above in their expert reports/declarations. Both agree that, under DSHEA, there is no premarket approval requirement for dietary supplements. Wenik Decl., Ex. 34, Deposition of Dennis Keefe ("Keefe Dep.") 74:8-74:12; Ex. 35, Deposition of Cara Welch ("Welch Dep.") 72:10-72:15. They further agree that, under DSHEA, the burden is on the FDA to prove that a dietary supplement/ingredient is unsafe. *Id.* Keefe Dep. at 74:13-74:17; Welch Dep. at 72:16-72:24; 73:5-73:15. *See also* Wenik Dec. Ex. 5, Fabricant Dep. (former head of FDA Dietary Supplements Division), at 81:24-81:25; 154:17-155:16 (no premarket approval requirement, burden on FDA to show a dietary supplement/ingredient is unsafe). Once again, under this framework, DMAA is a lawful, safe dietary ingredient that is incorporated into various Hi-Tech dietary supplement products, and is not subject to seizure or forfeiture.

B. DMAA Is Safe.

First and foremost the Government has not and cannot prove that DMAA is unsafe, i.e., that there is "an unreasonable risk of illness or injury under [its] conditions of use recommended or suggested in labeling." 21 U.S.C. § 342(f)(1)(A). The only scientific evidence that the Government can point to that remotely suggests a safety concern about DMAA are published Case Reports or unpublished Adverse Event Reports which purport to show a temporal connection between DMAA and an injury or death. None of these establish a legitimate safety issue for DMAA.

Not a single serious illness or death has been shown to have been caused by DMAA. That this is so is perhaps best reflected in the District Court decision which rejected as unreliable and unfounded the testimony of the plaintiff's experts in the wrongful death case of Michael Sparling that his death was caused by DMAA. Wenik Decl., Ex. 36, Order, *Sparling v. Doyle, et al.*, Dkt. No. EP-13-CV-323-DCG (W.D. Tex. July 27, 2015). Epidemiologists and toxicologists recognize that Case Reports and Adverse Event Reports can rarely establish that a substance causes an injury or death because of confounding factors such as contemporaneous ingestion of illegal drugs or other dietary supplements. Wenik Decl., Ex. 2, Lumpkin Decl. at ¶¶ 94-96; Ex. 37, Declaration of Mitchell Elkind ("Elkind Decl.") at ¶¶ 75, 85. This is particularly true of DMAA where the FDA

itself has publicly admitted that adverse events temporally associated with DMAA were not necessarily caused by DMAA. Wenik Decl., Ex. 19, April 27, 2012 Press Release ("The agency has received 42 adverse event reports on products containing DMAA. While the complaints do not establish that DMAA was the cause of the incidents…").[5] Moreover, in many instances DMAA Case Reports have involved the abuse of DMAA with individuals consuming it in vastly greater quantities than called for in dietary supplements such as those marketed by Hi-Tech.[6] Such misuse cannot satisfy the Government's burden to show that DMAA is unsafe under the conditions of use recommended on Hi-Tech product labeling.

---

[5] Claimants' expert, Dr. Marvin Heuer noted his skepticism of Adverse Event Reports stating that they are often a function of publicity rather than evidence of causation. Wenik Decl., Ex. 38, Heuer Declaration at ¶ 77. This is certainly true regarding DMAA. When the FDA issued warning letters and press releases regarding DMAA it was aware of 42 adverse events that had occurred regarding DMAA in the several years it had been in the marketplace as a dietary supplement ingredient. Wenik Decl., Ex. 19, April 27, 2012 FDA Press Release. Less than a year after this publicity, the number of adverse events had more than doubled to 86. Wenik Decl., Ex. 39, GOV-007908-GOV-007910 (April 30, 2013 DMAA Q&A).

[6] For example, Amy Eichner testified that her concerns regarding DMAA stemmed in large part from Case Reports she had read by New Zealand researcher Paul Gee. Wenik Decl, Ex. 4, Eichner Dep. at 28:4-28:19. The individuals in Dr. Gee's Case Reports typically consumed "party pills" which contain dramatically more DMAA than Hi-Tech products consumed at their recommended doses. *See, e.g.*, Wenik Decl., Ex. 40, Gee, *Another bitter pill: a case of toxicity from DMAA party pills*, Vol. 123 The New Zealand Medical Journal 124 (December 17, 2010) (individual consumed 2 capsules of DMAA "party pills" each of which contained 278 mg of DMAA per capsule).

By contrast, there is a substantial amount of scientific research that points to DMAA's safety. In the wake of serviceman Michael Sparling's death, the Department of Defense ("DOD") conducted a comprehensive case control study of DMAA involving hundreds of cases. Among other things, the study, completed in June 2013, found: 1) it was unlikely that DMAA played a significant role in the deaths of four service personnel who had consumed DMAA, 2) there was no statistically significant association between DMAA use and adverse medical events or outcomes, and 3) soldiers consuming DMAA had 40% **lower** odds of having an adverse medical outcome. Wenik Decl., Ex. 41, Col. John Lammie, Report of the Department of Defense 1,3 Dimethylamylamine (DMAA) Safety Review Panel, June 3, 2013 (the "DoD Study"), stamped GOV-02688 through GOV-02796, at GOV-002714-15, GOV-002736. Similarly, several peer reviewed studies examined the physiological effects of DMAA and found, at worst, transient increases in blood pressure that did not have clinical significance. Wenik Decl., Ex. 37, Elkind Decl. at ¶¶ 52-68; Ex. 2, Lumpkin Decl. at ¶¶ 43-54; 68-75.

Perhaps most importantly, there is a dearth of expert testimony in the record to challenge the safety of DMAA. Claimants have presented a comprehensive slate of experts as to DMAA's safety including a toxicologist, Dr. Michael Lumpkin, a pharmacologist/physician, Dr. Matthew Lee, a board certified neurologist, Dr. Mitchell Elkind, and a family medicine physician, Dr. Marvin

Heuer. All agree that Hi-Tech's DMAA containing products are safe when used as recommended.

The Government has presented no clinicians or safety experts regarding DMAA. The only Government expert that attempts to address DMAA's safety is one of the Government's regulatory experts, Dr. Dennis Keefe. Dr. Keefe is a non-clinician, Wenik Decl., Ex. 34, Keefe Dep. at 68:4-68:6, whose academic training was focused on the cellular structure of plants. *Id.* at 72:8-72:19.

With regard to DMAA's safety, Dr. Keefe's testimony/opinions borders on the ludicrous. Dr. Keefe did not consult with any other expert or scientist regarding DMAA's safety, but rather, relied on his and his staff's review of the scientific literature. Wenik Decl., Ex. 34, Keefe Dep. at 41:25-42:15. In this regard, Dr. Keefe freely admitted that he had no training in either toxicology or pharmacology and was not an expert in the evaluation of any literature from those fields. *Id.* at 70:8-71:9. Similarly, he admitted that he was not an expert in the evaluation of scientific literature regarding physiology or any of the maladies that have been touched upon in DMAA Case Reports including, liver disease, kidney disease, cardiovascular disease, stroke or hypertension. *Id.*

Nevertheless, despite his lack of any qualifications to do so, Dr. Keefe reviewed DMAA physiology studies and Case Reports and provided his uninformed comments on the same in both his expert declarations/reports and

deposition.[7] These included, among other things, 1) suggesting that DMAA is associated with liver toxicity even though the articles he cited, and a Government indictment, suggested the liver injuries were caused by another substance, Aegeline, Wenik Decl., Ex. 34, Keefe Dep. at 127:3-127:23; 120:11-122:2; 2) simply ignoring articles that questioned the veracity of the information contained in DMAA Case Reports, *id.* at 114:5-115:23; and 3) concluding, even when confronted with the fact that DMAA did not even appear in the toxicology screen in a Case Report, that nevertheless the article raised "uncertainty as to the role of the safety of DMAA," *id.* at 143:20-145:21.

In any event, whatever weight should be given to Dr. Keefe's evaluation of DMAA safety information, the reality is that he does not offer an expert opinion as to the safety of DMAA at all. He does not point to any particular danger or harmful characteristic of DMAA. Rather, his opinion is limited to a supposed statutory assumption that DMAA is "deemed" unsafe because it is an unapproved food additive.[8] *Id.* at 50:6-51:13; 53:13-53:16. This does not meet the Government's burden to show an unreasonable risk of illness or injury for a dietary

---

[7] As just one example of Dr. Keefe's utter unsuitability to evaluate the safety of DMAA, he was not familiar with what the basic term "clinically significant" meant. Wenik Decl., Ex. 34, Keefe Dep. at 105:25-106:4.

[8] Claimants address the food additive issue in Point II infra.

ingredient. Indeed, as shown in Point II herein, Dr. Keefe's entire opinion is irrelevant as DMAA is not a food additive.

Finally, it is worth commenting on the practical realities regarding the FDA's attempt to regulate DMAA by intimidation as outlined in this litigation. The Government sent one of Hi-Tech's competitors, USP Labs, LLC, a warning letter about DMAA in April 2012. Wenik Decl., Ex. 3, United States' Responses to Requests for Admission at Request 2. USP Labs sent letters in response, and it was not until more than a year later, in April 2013, that the FDA finally sent a formal response to USP Labs. *Id.* at Request 4. All the while, USP Labs continued to sell DMAA-containing products to the public. *Id.* at Request 6. Similarly, the FDA has made no effort to physically remove DMAA containing products from Hi-Tech's facilities. *Id.* at Requests 12, 13. One would think that, if DMAA truly presented a health risk to the public, the Government would have proceeded otherwise.

C. Synthetically Produced DMAA Qualifies as a Dietary Ingredient.

In its warning letters to Hi-Tech competitors in April 2012, the FDA took the position that, to the extent dietary supplement products contained synthetically produced DMAA, they did not contain a "dietary ingredient" under DSHEA. *See, e.g.*, Wenik Decl., Ex. 42, April 24, 2012 Warning Letter from the FDA to USP Labs, LLC, stamped HT 00572-00574. The Government has since retreated from

that position. In its answer to Hi-Tech's Administrative Procedure Act Complaint, the United States admitted:

> …[S]ome dietary ingredients may be both naturally and synthetically produced, that FDA has recognized the equivalence of synthetic and natural vitamins, and that FDA has recognized that both synthetic and natural ingredients used in the food supply may be dietary substances and, therefore, dietary ingredients.

Answer (Doc. 52) at ¶ 14.

Similarly, the Government's regulatory expert, Dr. Cara Welch, testified that synthetic ingredients can be dietary ingredients under DSHEA.[9] Wenik Decl., Ex. 35, Welch Dep. at 27:7-27:23. Hi-Tech has stipulated that the DMAA used in its dietary supplements was synthetically produced. Doc. 58. As outlined above, so long as DMAA is found in a botanical, its synthetic sourcing has no bearing on whether or not it is a dietary ingredient under DSHEA.

D. Undisputed Expert Testimony Establishes that DMAA Is a Dietary Ingredient Present in the Food Supply Before October 15, 1994.

Claimants' expert, Dr. Marvin Heuer, has opined that geraniums have been in the food supply since before October 15, 1994 and that both geraniums and DMAA, as a constituent or extract of geraniums, are therefore dietary ingredients

[9] Dr. Welch is a current FDA employee in a senior, policy-making position. Wenik Decl., Ex. 35, Welch Dep. at 40:6-40:15.

pursuant to DSHEA. Wenik Decl., Ex. 38, Declaration of Marvin Heuer ("Heuer Decl.") at ¶¶ 51-53; 90-93. Dr. Heuer is uniquely qualified to offer this opinion. In addition to being a practicing physician, he has served as a senior R&D executive/scientist at multiple Fortune 500 drug companies, *id*. at ¶ 23, as well as with one of the world's largest dietary supplement companies, Iovate. *Id*. at ¶¶ 7-10. His consulting firm has provided advice to drug companies and dietary supplement companies on regulatory issues related to dietary supplements and the status of dietary ingredients for years. *Id*. at ¶¶ 16-22.[10]

Dr. Heuer's opinions, in essence, remain unrefuted by the Government's experts. One of the Government's chemistry experts, James Kababick, has opined that geraniums have been used as a flavoring for over 100 years. Wenik Decl., Ex. 43, Kababick Rebuttal Report, at ¶ 13. The Government's regulatory expert, Dr. Cara Welch, testified that both geraniums and their constituents and extracts are

---

[10] Dr. Heuer's opinions find further support in the fact that no new dietary ingredient notifications ("NDI") were ever filed with the FDA for DMAA. Wenik Decl., Ex. 3, United States' Responses to Requests for Admissions, at Request 20. Presumably, if any of the many companies in the dietary supplement industry that previously marketed DMAA containing products thought it had not been in the food supply prior to October 15, 1994, it would have filed an NDI. Similarly, companies responding to FDA's DMAA warning letters affirmed their belief that DMAA was a lawful dietary ingredient in the food supply prior to October 15, 1994. *See*, *e.g.*, Wenik Decl., Exs. 44-49, GOV-004339-GOV-004340; GOV-004343-GOV-004344; GOV-004345-GOV-004346; GOV-004347-GOV-004355; GOV-004771-GOV-004777; GOV-004778-GOV-004779.

dietary ingredients under DSHEA. Wenik Decl., Ex. 35, Welch Dep. at 77:25-78:15.

As to whether DMAA specifically is a dietary ingredient as an extract or constituent of geraniums pursuant to DSHEA, the Government's regulatory experts declined to offer an expert opinion, perhaps because such opinions would not have been favorable to the Government's litigation theories. Dr. Welch was quite explicit that, with regard to 21 U.S.C. § 321(ff)(1)(F), the section of DSHEA which provides that constituents or extracts of botanicals qualify as dietary ingredients, she was **not** offering an expert opinion one way or the other as to DMAA. Wenik Decl., Ex. 35, Welch Dep. at 74:9-75:8. Similarly, the Government's other regulatory expert, Dr. Dennis Keefe, testified that he was not personally opining as an expert that DMAA was not a dietary ingredient but rather relying on the views of unnamed others for that conclusion. Wenik Decl., Ex. 34, Keefe Dep. at 98:21-99:1. Thus, there is no expert regulatory opinion offered by the Government to refute the expert opinion of Dr. Heuer.

In sum, DMAA meets all the attributes of a dietary ingredient set forth in DSHEA and there is no basis for the United States' seizure of it. It was in the food supply prior to October 15, 1994. It is an extract or constituent of a botanical, i.e., geraniums. Whether the DMAA used by Hi-Tech was extracted from plants or synthetically produced is of no moment. Finally, DMAA is safe. The Government

has not event attempted to meet its burden to show that DMAA presents an "unreasonable risk of illness or injury." Accordingly, the United States' seizure complaint should be dismissed and the detention of Claimants' goods lifted.

II. The Products Detained by the United Sates Are Not Unapproved Food Additives and Therefore the Government's Seizure Action Should Be Dismissed.

In an effort to avoid its burden of proof under DSHEA to prove DMAA unsafe and therefore subject to seizure, the Government has unilaterally declared DMAA to be an "unapproved food additive." By this stratagem, the Government attempts to shift the burden of proof to the Claimants and avoid other procedural prerequisites that the Government must undertake to properly seize dietary ingredients that are purportedly unsafe. The Court should reject this ploy as DMAA is not a food additive; it is a dietary ingredient via its being a constituent or extract of geraniums, and the Government's evidence to the contrary is weak and/or tainted. Moreover, even if it were not a dietary ingredient, DMAA is still not subject to seizure as an "unapproved food additive" because, as set forth below, it would also qualify as Generally Recognized as Safe ("GRAS"), an exception to the statutory definition of "food additive."

A. DMAA Is a Constituent or Extract of Geraniums, Not a Food Additive.

The Government's regulatory expert, Dr. Dennis Keefe, admitted that an extract or constituent of a botanical is a dietary ingredient that is expressly

excluded from the definition of "food additive" (and thus not subject to regulation as a food additive). Wenik Decl., Ex. 34, Keefe Dep. at 93:18-96:11; *see also, id.*, Ex. 3, United States' Responses to Requests for Admission, at Request 25 ("food additives" do not include dietary ingredients/supplements by statute). Dr. Keefe's opinion that DMAA is an "unapproved food additive" and therefore "deemed unsafe" by statutes regulating food additives, Wenik Decl., Ex. 34, Keefe Dep. at 50:17-51:16, rests on a thin reed. Dr. Keefe is not personally opining on whether or not DMAA is in geraniums. *Id.* at 36:16-36:20; 55:3-55:5. Rather, he asserts, without any citation or support, that "information available to FDA" establishes that DMAA is not a dietary ingredient. *Id.* at 96:12-97:7; Wenik Decl., Ex. 50, Keefe Initial Declaration, at ¶ 40. This "information" is the purported "absence of convincing information that DMAA exists in a geranium." Wenik Decl., Ex. 34, Keefe Dep. at 97:15-97:17. However, Dr. Keefe is not personally opining that DMAA is not in geraniums but rather relying on the expertise of unnamed others. *Id.* at 98:21-99:2.

To the extent Dr. Keefe is relying on the Government's chemistry experts, that reliance is misplaced. As detailed at length in Claimants' accompanying motions to exclude James Kababick, Dr. Ikhlas Khan and Dr. Paula Brown, the opinions of the Government's chemistry experts that DMAA cannot be found in geraniums are unreliable and should be excluded. For that reason alone, the

Government's seizure action should be dismissed because, without expert testimony, the Government cannot establish DMAA is a food additive subject to seizure.

Even if the Court were to consider the Government's chemistry experts, the result would be the same. As noted by the Supreme Court in *Anderson*, summary judgment should be granted when the evidence is so one-sided that one party must prevail as a matter of law. 477 U.S. at 251-52. Such is the case with the issue of whether DMAA is in geraniums.

Claimants retained one of the researchers who studied DMAA prior to this litigation to provide an expert opinion, Dr. Paul Simone. Dr. Simone, an expert chemist, has testified unequivocally that his research conducted at the University of Memphis detected DMAA in multiple geranium samples. Wenik Decl., Ex. 51, Declaration of Paul Simone at ¶ 73; Ex. 52, Deposition of Paul Simone at 116:19-22. His published research joins two other published articles that detected DMAA in geraniums, the so-called "Ping Study" and the "Li Study." *See* Wenik Decl., Ex. 53, Ping, *A Study On The Chemical Constituents Of Geranium Oil*, 25 Journal of Guizhou Institute of Technology, February 1996; Ex. 23, Li, *Identification and Quantification of Dimethylamylamine in Geranium by Liquid Chromatography Tandem Mass Spectrometry*, Analytical Chemistry Insights 2012:7 47-58.

The Government's experts attempt to refute the opinions of Dr. Simone and the research of others who have detected DMAA in geraniums by making five arguments: 1) older research on geraniums did not detect DMAA; 2) Dr. Simone's and others' results detecting DMAA must be due to either tampering with or contamination of the geranium samples studied; 3) the "larger body" of research does not report finding DMAA in geraniums; 4) research that detected DMAA in geraniums is somehow compromised because it was sponsored by a Hi-Tech competitor, USP Labs; and 5) Claimants cannot show a biosynthetic pathway in geraniums for DMAA. None of these arguments withstands even modest scrutiny.

The fact that DMAA is not reported in older published research examining geraniums is neither surprising nor relevant. As the Government's chemistry experts admitted, geraniums are complex and contain scores of compounds/components. Wenik Decl., Ex. 54, Deposition of James Kababick ("Kababick Dep.") at 86:13-86:87:14 (well over 100 components); Ex. 11, Khan Dep. at 74:20-75:2 (there are hundreds of substances in geraniums, only about 90 of which have been identified). Moreover, as also admitted by the Government's experts, it is only in recent years that scientists have developed standards for DMAA and accurate methods to detect it. *See* Wenik Decl., Ex. 55, Initial Declaration of Paula Brown ("Brown Initial Decl.") at p5 (new methods developed to detect DMAA in geranium raw materials since its introduction into dietary

supplements); Wenik Decl., Ex. 54, Kababick Dep. at 110:7-11:6 (Kababick recently developed method to detect and quantify DMAA); Wenik Decl., Ex. 11, Khan Dep. at 94:24-95:9 (Khan developed new method to detect DMAA); Ex. 14, ElSohly 4330-4335 (ElSohly developed new sensitive detection method). Thus, the explanation as to why older research regarding geraniums did not show DMAA is simply that scientists were not specifically looking for the substance nor were they equipped with the tools to do so.

As to the alleged tampering with or contamination of geranium samples used by Dr. Simone and others who detected DMAA, it is important to remember that, in the context of summary judgment, speculation does not create a genuine issue of material fact. *Eubanks*, 626 Fed. Appx. at 253; *Cordoba*, 419 F.3d at 1181. The Government's experts' opinions in this regard are simply inadmissible rank speculation. They all conceded that there is no evidence of tampering with or contamination of the samples used by researchers who detected DMAA in geraniums. *See* Wenik Decl., Ex. 54, Kababick Dep. at 150:24-151:5; 160:3-160:22 (no evidence of tampering or contamination); Ex. 56, Brown Dep. at 147:6-1478:18 (no evidence of contamination); Ex. 11, Khan Dep. at 223:15-223:23 (no evidence of contamination).

The contention that the larger body of scientific research did not detect DMAA in geraniums, *see, e.g.*, Wenik Decl., Ex. 55, Brown Initial Decl. at p5

("majority of studies conducted thus far have not detected the compound in geranium); Ex. 43, Kababick Rebuttal Report at ¶¶ 16-17 (same), is simply false. As discussed in detail in prior motion practice and the accompanying motions to strike the Government's chemistry experts, while it may be true that the majority of "published results" do not reflect the detection of DMAA in geraniums, we now know from vigorous discovery that many of the studies at issue intentionally suppressed positive findings of DMAA in geraniums.

We begin with the first DMAA study of the Government's expert, Dr. Ikhlas Khan, *Pelargonium Oil and Methyl Hexaneamine (MHA): Analytical Approaches Supporting the Absence of MHA in Authenticated Pelargonium graveolens Plant Material and Oil*, Journal of Analytical Toxicology (2012). *See* Wenik Decl., Ex. 15, GOV-027840-GOV-027854. We now know that Dr. Khan and his colleague, Dr. Mahmoud ElSohly, developed a very sensitive method for detecting DMAA for purposes of this study and did detect low levels of DMAA in geraniums samples. *See* Wenik Decl., Ex. 13, May 2011 email correspondence among Amy Eichner, Dr. ElSohly, and Dr. Khan regarding Dr. ElSohly's detection of DMAA in geranium, stamped ElSohly 4318-4322. Rather than report this in the published article, these "scientists" conspired with the USADA to simply change the reporting detection limit in the published article so as to show no DMAA detected. *See* Wenik Decl., Ex. 14, June 2011 email correspondence among Amy

Eichner, Dr. ElSohly, Dr. Khan, and Larry Bowers regarding Dr. ElSohly's detection of DMAA in geranium, stamped ElSohly 4330-4335.

Similar chicanery occurred with the Zhang/Armstrong article of 2012, which also reported no detection of DMAA in its published version. *See* Wenik Decl., Ex. 18, the published version of "1,3-Dimethylamylamine (DMAA) in supplements and geranium plants/products: natural or synthetic?", a 2012 DMAA study by Ying Zhang and Daniel Armstrong, stamped ElSohly 2600-2604. The published version of this study was completely re-written from its original form which, among other things, noted the detection of DMAA in significant amounts in two of eight geranium samples. Wenik Decl., Ex. 17, ElSohly 1738-1743. Amy Eichner had access to the original unpublished version, and she forwarded it to Drs. Khan and ElSohly. Wenik Decl., Ex. 16, May 2012 email correspondence among Amy Eichner, Dr. ElSohly, and Dr. Khan containing an unpublished version of "1,3-Dimethylamylamine (DMAA) in supplements and geranium plants/products: natural or synthetic?", a 2012 DMAA study by Ying Zhang and Daniel Armstrong, stamped ElSohly 2181-2190. She admitted the "possibility" that either she or a colleague at the USADA had communicated with the study's authors about this "embargoed" draft to "try and understand" it. Wenik Decl., Ex.4, Eichner Dep. at 147:13-149:14. Remarkably, or perhaps not surprisingly, after having been forwarded by Eichner to Dr. Khan, the original draft of the

Zhang/Armstrong study disappeared from public view, to be replaced by the version claiming no DMAA had been detected. *Compare* Wenik Decl., Ex. 17, ElSohly 1738-1743; *with* Ex. 18, ElSohly 2600-2604.

Finally, as discussed at length in Claimants' other motion papers regarding Dr. Khan, the 2014 Multi-Center Study, Wenik Decl., Ex. 25, "*Methylhexanamine is not detectable in Pelargonium or geranium species and their essential oils: A multi-center investigation*," Drug Testing and Analysis (2014), 7(7), 645-54 (the "Multi-Center Study"), which was supposed to be the definitive word on whether or not DMAA could be detected in geraniums, intentionally omitted data from one of its four laboratories that detected DMAA in multiple geranium samples. *See* Wenik Decl., Ex. 26, correspondence from Min Yang of the Shanghai Institute of Materia Medica notifying Dr. Khan of the detection of DMAA in geranium the Multi-Center Study, stamped ElSohly 2267-2272; Ex. 11, Khan Dep. at 135:3-151:20. As with their 2012 study, Dr. Khan and Dr. ElSohly achieved this sleight of hand by simply adjusting the detection limits in the published article to suppress positive findings of DMAA in geraniums. *Id.*

Thus, the contention that the majority or larger body of evidence did not detect DMAA is in large part a product of manipulation on the part of the Government's experts and is simply untrue. Indeed, it's worse than the suppression and manipulation of study results described above. The Government's

experts simply ignored, rather than analyze or explain, any evidence that DMAA is found in geraniums. Government expert James Kababick conveniently omitted from his report that he personally detected DMAA in geranium samples he obtained from China. Wenik Decl., Ex. 54, Kababick Dep. at 58:17-59:17. In an official report, the Government of New Zealand concluded that it was likely that DMAA was a naturally occurring constituent of geraniums. Wenik Decl., Ex. 57, July 2015 Classification of 1,3-dimethylamylamine, at 3. This too was ignored by the Government's experts. In emails to Drs. Khan and ElSohly, Amy Eichner noted that, one of the labs used by the USADA, Banned Substance Control Group, had detected DMAA in geranium oil samples provided by the USADA, and she sought advice from Drs. Khan/ElSohly about this. Wenik Decl., Ex. 4, Eichner Dep. at 130:2-132:2. Of course, the fact that yet another laboratory had detected DMAA in geraniums did not make its way into Dr. Khan's export report.

Regarding USP Labs, Claimants do not dispute that USP Labs sponsored research conducted by Drs. Li and Simone which detected DMAA in geraniums. However, the Government's experts can point to no consequences from this fact that would cast doubt either on the results obtained by Drs. Li and Simone or the fact generally that DMAA can be found in geraniums. As Government expert Dr. Cara Welch admitted, the fact that a commercial enterprise sponsors/funds scientific research does not necessarily imply anything negative about the quality

or results of said research. Wenik Decl., Ex. 35, Welch Dep. at 31:14-32:9. Moreover, as described above, the facts are that, multiple researchers, using geranium samples from multiple sources, also detected DMAA in geraniums, lending credence to the USP Labs sponsored research. Indeed, if anything, given the shameful actions of Government sponsored researchers, it is the conduct of the USADA, FDA and the DOJ that raises questions as to integrity, while there is no evidence in the record that USP Labs did anything to compromise scientific research.

Finally, similar to their arguments regarding imagined "contamination" of geranium samples, the Government experts' contention that there is no biosynthetic pathway in geraniums to produce DMAA is nothing more than rank speculation. It is undisputed that scientists have not identified all of the biosynthetic pathways for plants. *See* Wenik Decl., Ex. 54, Kababick Dep. at 84:18-84:22; Ex. 56, Brown Dep. at 60:5-60:11. Government expert James Kababick, who has published no research whatsoever on geraniums, Wenik Decl., Ex. 54, Kababick Dep. at 12:22-13:4, and is not an expert on biosynthetic pathways, *id.* at 84:13-84:17, has simply nothing to offer on the issue of biosynthetic pathways other than his having read Government expert Paula Brown's comments on the issue **after** he authored his report. *Id.* at 141:10-141:19.

As for Dr. Brown, she has conducted no studies or analysis of DMAA, Wenik Decl., Ex. 56, Brown Dep. at 55:6-55:20, nor has she conducted any study or analysis of geraniums, *id.* at 56:4-56:8. Dr. Brown was aware of no scientific study or analysis that attempted to identify the biosynthetic pathway(s) for geraniums to produce DMAA. *Id.* at 58:13-59:13. Rather, she examined textbooks and literature generally about the biosynthetic pathways of plants generally and, not being able to find a published pathway that, in her mind, would match one that should be in geraniums to produce DMAA, she leapt to the conclusion that there is none. *Id.* at 128:21-129:20; 130:8-131:23.

Such an illogical conclusion, devoid of any facts, is simply inadmissible, unhelpful speculation and is contradicted by the simple fact that DMAA has been repeatedly found in geraniums, both by researchers cited by the Government and the Claimants. Unless one wants to accept the Government's absurd hypothesis that geranium samples, from multiple sources and multiple regions, collected at different times and by different people, have all been contaminated to produce false DMAA positive results, the conclusion is inescapable that DMAA is a natural constituent of geraniums.

B. DMAA Is GRAS and Thus Not a Food Additive.

In addition to his opinion that "dietary ingredients" are **not** food additives and therefore not subject to regulation as same, Government regulatory expert Dr.

Dennis Keefe also noted that substances which are GRAS are also not food additives and thus not covered by the statutes and regulations regarding same. Wenik Decl., Ex. 34, Keefe Dep. at 79:9-79:14. In this regard, as Dr. Keefe noted, a substance can qualify as GRAS without any FDA opinion on the issue and without a company providing to the FDA any information to support a GRAS determination. *Id.* at 81:17-81:24. In other words, a dietary supplement manufacturer or distributor can self-affirm that a substance/ingredient is GRAS, and there is no obligation on the company to report that self-affirmation to the FDA. *Id.* at 75:7-75:17. DMAA is GRAS, there was no obligation on Claimants' part to inform FDA of that fact before this litigation, and therefore the Government cannot seize and forfeit Claimants' goods as unapproved food additives.

As described in Point I A above, there is extensive evidence that supports the safety of DMAA.[11] As Dr. Keefe testified, while information to support a GRAS determination must be publicly accessible, it need not be peer-reviewed, published articles. *Id.* at 155:7-155:11. Information supporting a GRAS determination need not be human clinical trials, nor is there any minimum duration

[11] Claimants' expert toxicologist, Dr. Michael Lumpkin, provided a detailed summary of the animal studies, clinical research, the DOD case control study and other evidence that supports the safety of DMAA at the dosages recommended by Hi-Tech and other dietary supplement companies. *See* Wenik Decl., Ex. 2, Lumpkin Decl.

or number of study subjects required to support a GRAS determination. *Id.* at 45:4-45:15. When determining whether something is GRAS, the conditions of use are examined including how much of the substance is expected to be consumed and, if there are labels, what warnings are provided. *Id.* at 49:19-50:3.

Claimants presented the expert opinions of a physician/scientist, who has extensive experience with GRAS determinations, Dr. Marvin Heuer, who opined that DMAA is GRAS. Wenik Decl., Ex. 38, Heuer Decl. at ¶¶ 37-39; 63. Similarly, Claimants presented expert opinions from a physician/pharmacologist that DMAA is GRAS. Wenik Decl., Ex. 58, Declaration of Matthew Lee, M.D. at ¶¶ 55(b), 59; Ex. 59, Deposition of Matthew Lee at 69:14-16.

While the Government may argue otherwise, it has not presented any expert testimony to refute the GRAS conclusions of Claimants' experts. Claimants take no issue with Dr. Keefe's qualifications to testify as a regulatory expert regarding, among other things, GRAS procedures at the FDA and the types of information the FDA considers regarding GRAS issues. However, as noted above, Dr. Keefe has no expertise in toxicology, pharmacology, physiology or other topics germane to determining a substance's safety. As Dr. Keefe testified, chemistry, biochemistry, toxicology, microbiology and other areas are relevant to GRAS determinations. Wenik Decl., Ex. 34, Keefe Dep. at 38:16-38:25. Dr. Keefe was not presented as an expert in chemistry, toxicology, or any other topic key to making a GRAS

determination. Simply put, while Dr. Keefe may be qualified to testify as to the sorts of information the FDA can and will consider in resolving a GRAS issue, he is not qualified to evaluate such information as an expert.

For reasons known only to the Government, it has presented no experts on safety in this matter: no clinicians, no pharmacologists, no toxicologists, nor any similarly qualified scientist. Claimants have. It may well be that Dr. Keefe relied on the expertise of others with the appropriate qualifications to evaluate scientifically the safety of DMAA and whether it was GRAS:

> Q: Did you discuss DMAA's safety with any cadre of experts or scientists?
>
> A: We examined the published literature on DMAA and the safety of DMAA when used in food.
>
> Q: When you say "we," that means you, I take it?
>
> A: FDA. FDA, my office, my staff.
>
> Q: For purposes of preparing this expert report?
>
> A: Yes.

Wenik Decl., Ex. 34, Keefe Dep. at 41:25-42:11.

The problem for the Government is that it never disclosed any reports or opinions from these unnamed experts who assisted Dr. Keefe. Thus, Claimants' expert testimony on GRAS is unrebutted, and the Court must hold that DMAA is not a food additive because it is GRAS.

III. The Government Engaged in and Abetted Scientific Dishonesty and Deceit and Claimants Are Therefore Entitled to Summary Judgment on Their Claims of Violation of Due Process and the Administrative Procedure Act.

The Government's gambit in unilaterally declaring DMAA to be a food additive, rather than a dietary ingredient, enabled it to bypass several procedural safeguards to the detriment of Claimants. While that conduct in and of itself would justify relief, the situation is compounded by the Government's involvement in actions designed to suppress scientific findings that undercut DMAA's classification as a dietary ingredient. No doubt, government officials felt justified in their actions. For example, FDA official Dr. Daniel Fabricant felt that DMAA posed a danger as a "drug" that had been introduced into the food supply. Wenik Decl., Ex. 5, Fabricant Dep. at 67:22-68:4. While this attitude may explain the Government's misconduct, the ends do not justify the means. The unlawful participation by the Government in scientific dishonesty and deceit compels the granting of the relief demanded by Claimants in their Administrative Procedure Act Complaint.

As noted above, the burden is on the Government to prove a dietary ingredient is unsafe under DSHEA. Declaring DMAA a "food additive" is an attempt by the Government to bypass that burden and shift it to the Claimants. However, it goes much further than that. Pursuant to 21 U.S.C. § 342(f)(2), **before**

the Government can initiate a civil proceeding against a dietary ingredient or supplement, it must give the adverse party notice and an opportunity to present views orally and in writing. It is undisputed that Claimants were not afforded that right here. *See* Wenik Decl., Ex. 3, United States' Reponses to Requests for Admission, at Request 9.

Similarly, the Government proceeded via warning letters unilaterally declaring that DMAA was not a dietary ingredient under DSHEA.[12] Essentially, the Government was attempting to remove DMAA from the marketplace via this intimidation. By the Government's own admission, banning a lawful dietary ingredient is a lengthy process that requires rulemaking, notice and comment. Wenik Decl., Ex. 39, Q&A on DMAA in Dietary Supplements, GOV-007908-GOV-007910); Ex. 60, Q&A on Dietary Supplements, HT00563-HT00566; Ex. 5, Fabricant Dep. at 162:6-162:20. It is undisputed that no such process took place here regarding DMAA. *See* Answer (Doc. 52) at ¶ 16. By simply declaring DMAA to not be a dietary ingredient, the Government was able to ignore this burden.

[12] It is undisputed that Claimants did not have the benefit of a warning letter either in this matter. *See* Wenik Decl., Ex. 3, United States' Responses to Requests for Admission, at Request 7.

Perhaps all of the above would not be problematic if the Government possessed definitive evidence that DMAA was not a dietary ingredient. However, not only did it not possess such evidence, it was complicit in a scheme to suppress evidence demonstrating that DMAA was and is a lawful dietary ingredient. Under the Administrative Procedure Act, agency action can be set aside where it is arbitrary, capricious, an abuse of discretion, contrary to right or in excess of authority. 5 U.S.C. §§ 706(2)(A)-(C). In other words, the agency's action must have been willful and unreasoning, without consideration and in disregard of facts and circumstances of the case. *See Plaza Bank of West Port v. Board of Governors of Federal Reserve System*, 575 F.2d 1248 (8th Cir. 1978). The Government's actions were all of these things.

First, it is important to note that the National Center for Natural Products Research ("NCNPR"), through which much of the controversial research discussed here was conducted, was and is an arm of the Government. The FDA provided millions of dollars in funding to the NCNPR. *See* Wenik Decl., Ex. 35, Welch Dep. at 49:4-49:21; 51:20-52:6; Ex. 5, Fabricant Dep. at 61:12-62:25. Its research activities were directed and approved by government officials who served as its project officers, first Dr. Daniel Fabricant, Wenik Decl., Ex. 11, Khan Dep. at 38:2-38:7; 35, Welch Dep. at 53:14-53:20; 5, Fabricant Dep. at 53:22-54:13; and later Dr. Cara Welch. Wenik Decl., Ex. 11, Khan Dep. at 36:23-37:11; Ex. 35,

Welch Dep. at 50:12-50:20. NCNPR officials, notably the Government's expert, Dr. Khan, regularly communicated with FDA officials about the status and progress of their research and sent draft manuscripts to the FDA for review. Wenik Decl., Ex. 35, Welch Dep. at 51:3-51:14; 52:7-53:2; Ex. 11, Khan Dep. at 36:23-37:25. Indeed, Dr. Khan even referred to Dr. Daniel Fabricant of the FDA as his "boss." Wenik Decl., Ex. 61, June 21, 2012 email string. The FDA had a close relationship with Drs. Khan/ElSohly and the NCNPR. Indeed, Drs. Khan/ElSholy even provided training for FDA inspectors. Wenik Decl., Ex. 5, Fabricant Dep. at 122:7-122:22.

The FDA/Government was directly involved with Dr. Khan to craft research to refute other scientists' work that found DMAA in geraniums. Dr. Khan provided a "strategy" to Dr. Daniel Fabricant of the FDA for what ultimately became the 2014 Multi-Center Study. Wenik Decl., Ex. 23, August 9, 2012 email to Dan Fabricant. Dr. Fabricant approved Khan's strategy for the new study. Wenik Decl., Ex. 24, August 9, 2012 email to Ikhlas Khan, 009960-009961.

As noted herein, Dr. Khan, Dr. ElSohly and the NCNPR suppressed positive findings of DMAA in both their 2012 and 2014 studies. Dr. Khan attempts to distance himself from both of these instances by claiming that the DMAA detected in the first study was the result of some unidentified impurity/contamination revealed through confirmation testing. Of course, no such confirmation testing or

contamination was disclosed in the published paper. Wenik Decl., Ex. 11, Khan Dep. at 109:5-112:6. Similarly, Dr. Khan claims that the positive DMAA results in his 2014 study were later refuted by confirmation testing which did not appear in that published paper either. *Id.* at 141:17-151:20. Needless to say, Claimants' expert has not been able to locate these supposed additional test results, they were not in materials obtained from either the University of Mississippi or Dr.ElSohly, and Claimants have not received any such test results in discovery from the Government.

As also discussed above, the Zhang study, conducted at the University of Texas with researcher Daniel Armstrong, was also completely revised after it came into the hands of Drs. Khan and ElSohly.

It is enough to say that Drs. Khan and ElSohly, as officials of the NCNPR, a government funded entity, acted as agents of the Government and therefore the Government is accountable for their misconduct. However, it strains credulity to not believe that FDA officials were contemporaneously aware of the shenanigans going on with DMAA test results in a concerted effort to deprive it of its status as a dietary ingredient. Both Dr. Fabricant and William Martin of the FDA were aware as early as July 16, 2012 that there were two versions of the Zhang/Armstrong study, one finding DMAA and one not. Government expert James Kababick, who had been lobbying for action against DMAA as early as January 2012, Wenik

Decl., Ex. 62, January 2012 correspondence between James Kababick and Daniel Fabricant, stamped GOV-007705 through GOV-7706, was part of this dialogue. *See* Wenik Decl., Ex. 63, July 2012 correspondence between James Kababick and the FDA, stamped GOV-007710 through GOV-007712. Dr. Fabricant of the FDA admitted talking generally to Kababick about DMAA. Wenik Decl., Ex. 5, Fabricant Dep. at 102:13-102:24.

It would not be surprising to learn that the FDA was also aware of the omission of positive DMAA test results from the 2012 Khan study that had been solicited and organized by Amy Eichner. As Dr. Fabricant of the FDA testified, Eichner emailed him her opinions regarding DMAA. He also spoke with her via telephone of her concerns that DMAA was a health risk and was also aware of her giving speeches in 2011 and 2012 about the purported dangers of DMAA. Wenik Decl., Ex. 5, Fabricant Dep. at 52:2-53:21. Similarly, Dr. Fabricant testified that he regularly sought out the advice of both Drs. Khan and ElSohly, scientists whose judgment he trusted. *Id.* at 65:65-66:6; 66:11-67:8. Both Drs. Khan and ElSohly thought DMAA was dangerous, and both thought, even before they conducted what became their 2012 Study, that DMAA was not in geraniums. *Id.* at 126:23-127:6; 128:3-130:16.

The inference that Dr. Fabricant of the FDA was aware of the manipulation of the data for what ultimately became the 2014 Multi-Center Study is even more

compelling. Dr. Fabricant was having conversations with Dr. Khan to be kept updated about Dr. Khan's new DMAA research. Wenik Decl., Ex. 5, Fabricant Dep. at 163:18-164:12. In April of 2013, Drs. Khan and ElSohly were desperately seeking clarification of positive DMAA test results received from one of their laboratories in China because they were preparing to present their results at a conference. Wenik Decl., Ex. 26, email chain, ElSohly 2267-2272. Dr. ElSohly gave a PowerPoint presentation a week later at a conference held at the University of Mississippi where he falsely stated that DMAA was not detected in samples from China. *Compare* Wenik Decl., Ex. 26, email chain at ElSohly 2270 (DMAA detected in samples 13040, 13041, 13047, 13048 and 13049) with Ex. 27, 2013 ElSohly PowerPoint Slides, Fabricant Ex. 38 at page 31 (DMAA "not detected" in these samples). Dr. Fabricant was a chair of the conference, attended Dr. ElSohly's presentation and obtained a copy of the PowerPoint slide deck for the FDA. Wenik Decl., Ex. 5, Fabricant Dep. at 175:7-175:24; 176:8-177:3; 177:25-178:6. Though he claimed not to recall whether Drs. Khan and ElSohly had shared the manipulated data with the FDA, *id.* at 183:2-183:8, it defies belief to think that Dr. Fabricant and the FDA were not made aware of the manipulation of this data and its omission from the published version of the 2014 Multi-Center Study.

In sum, Claimants were deprived of procedural safeguards and their due process rights to protect their property by the Government inappropriately and without a factual or legal basis declaring DMAA to not be a dietary ingredient and therefore subject to seizure. The Government egregiously went a step further and, either through its agents the NCNPR and Drs. Khan and ElSohly and/or in collusion with them, suppressed and illegally manipulated scientific research results to make it appear that DMAA was not a constituent of geraniums to falsely support its position that the substance is not a dietary ingredient. Accordingly, summary judgment should be granted on Claimants' Administrative Procedure Act Complaint.

IV. The Government's Seizure Claim Against Purportedly Non-DMAA Containing Products Lacks Merit and Should be Dismissed.

As a backup to their primary contention that Hi-Tech's products are "adulterated" with DMAA, in Count Two of its Amended Complaint, the Government reverses course and alleges that two products detained at Hi-Tech, Fastin and "Geranium Powder," are misbranded items of food pursuant to 21 U.S.C. § 343(a)(1) because they do **not** contain DMAA. Doc. 25 at ¶¶ 22-24. Yet, as set forth below, the Government has failed to proffer any evidence of how the labels of Fastin and "Geranium Powder" are false, or how the labels are misleading or deceptive to consumers.

First, the Government alleges that Fastin's label stated or implied that it contained DMAA, or its chemical equivalent, but did not actually contain DMAA. Doc. 25 at ¶ 22. The Government further claims that Fastin is mislabeled in "that it contains 1,3 Dimethylamine HCL," but FDA's laboratory analysis did not reveal the presence of such ingredient in the product." *Id.*

In support of its contention that Fastin did not actually contain DMAA, the Government put forward the testimony of FDA chemist Dr. Rick Flurer to opine on the testing of Fastin that he performed in 2016, as well as the testing done by his supervisor, Dr. Samuel Gratz, in 2013. While Claimants' *Daubert* motion addresses the reliability and methodological issues with the FDA's testing of Fastin, what is clear is that the testing performed at the FDA lab failed to demonstrate that DMAA was not present in Fastin. Dr. Flurer admitted as much when he testified during his deposition that he "can't say that [DMAA] was not there [in the sample of Fastin that he tested]," Wenik Decl., Ex. 64, Flurer Dep. at 57:12-13. In fact, during his deposition, Dr. Flurer testified repeatedly that it is possible that DMAA was present below his reporting limit of 7.6 micrograms per tablet and below the reporting limit used by Dr. Gratz, which was not preserved and is unknown. Wenik Decl., Ex. 64, Flurer Dep. at 53:8-54:7; 57:12-19; 103:21-105:13; 106:12-23. Dr. Flurer also testified that he left this out of his report. *Id.* at 60:7-17.

Additionally, Dr. Flurer testified at his deposition that no one at the FDA tested for 1,3 Dimethylamine HCL, as it is a compound that doesn't exist. Wenik Decl., Ex. 64, Flurer Dep. at 67:18-69:6. The simple truth, as set forth in Claimants' motion to exclude Dr. Flurer, is that this was just a misspelling of DMAA.

Second, in support of its misbranding claim, the Government alleges that one of the seized Hi-Tech raw materials, labeled "Geranium Powder," did not actually contain DMAA. *See* Doc. 25 at ¶¶ 23-24. Dr. Flurer admitted that he did not see anything labeled "Geranium Powder" in preparation for his deposition testimony, and that he does not know anything about the FDA's tests related to "Geranium Powder." Wenik Decl., Ex. 64, Flurer Dep. at 69:7-70:5 (noting that Dr. Flurer's opinion does not encompass products labeled as "Geranium Powder" by Hi-Tech). Yet, there is no proof that the "Geranium Powder's" label is false, or that it stated or implied that it contained DMAA. Jared Wheat testified that he did not expect to see DMAA in tests results relating to "Geranium Powder," as he had purchased DMAA-free "Geranium Powder." Wenik Decl., Ex. 65, Wheat (30(b)(6) Dep.) at 99:18-107:13; *see also id*. at 73: 12-24 (noting that Hi-Tech "can have geranium powder that would not be where [we're] trying to sell a DMAA product, that could have other uses"). Given that the Government has not put forth any expert testimony setting forth how this particular batch of "Geranium Powder" is

misbranded, an area where "questions are raised that are beyond the common knowledge of a layperson," the Government's claims as set forth in Count Two fail. *Dukes v. State*, 428 F. Supp. 2d 1298, 1336 (N.D. Ga. 2006) (granting summary judgement for defendants where, after exclusion of plaintiff's experts, there was no other proffered expert testimony on complex medical questions).

Finally, Dr. Flurer testified at his deposition that he does not have any expertise in product labeling and was not offering an opinion regarding the product labels. Wenik Decl., Ex. 64, Flurer Dep. at 67:12-17. His only evidence that the Fastin label stated or implied that it contained DMAA was his self-serving, conclusory statement that he read the label. *Id*. at 66:14-67:10. Thus, the Government has failed to present any evidence on "consumer reaction" to these labels, or put another way, how the labels of Fastin and "Geranium Powder" mislead or deceive by stating or implying that they contain DMAA. *United States v. 119 Cases*, 231 F. Supp. 551, 559 (S.D. Fl. 1963) (rejecting government's misbranding contention of sugar as it failed to establish consumer reaction to the labels, and "the only evidence presented by the Government was the conjectural opinions of several of its nutrition witnesses"). Accordingly, given that there is no credible evidence that Fastin and/or "Geranium Powder" are misbranded, the Court should grant summary judgment, dismissing Count Two.

CONCLUSION

For the foregoing reasons, Claimants respectfully request that the Court enter an order dismissing the United States' seizure action, lifting the Government's detention of Claimants' goods, and granting summary judgment on the claims articulated in Claimants' Administrative Procedure Act Complaint.

Respectfully submitted,

/s/ Jack Wenik
Jack Wenik, Esq.
Epstein Becker & Green, P.C.
One Gateway Center, 13th Floor
Newark, New Jersey 07102
(973) 639-5221
jwenik@ebglaw.com
Admitted Pro Hac Vice

/s/ E. Vaughn Dunnigan
E. Vaughn Dunnigan, Esq.
E. Vaughn Dunnigan, P.C.
2897 N. Druid Hills Rd., Suite 142
Atlanta, Georgia 30329
(404) 663-4291
evdunnigan@hotmail.com
Georgia Bar No. 234350

/s/ Arthur Leach
Arthur Leach, Esq.
Law Offices of Arthur Leach
5780 Windward Parkway, Suite 225
Alpharetta, Georgia 30005
(404) 786-6443
art@arthurleach.com
Georgia Bar No. 442025

/s/ Bruce S. Harvey
Bruce S. Harvey
Law Office of Bruce Harvey
146 Nassau Street, NW
Atlanta, GA 30303
404-659-4628
Email: bruce@bharveylawfirm.com
Georgia Bar No. 335175

Attorneys for Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rules 5.1(C) and 7.1(D), I hereby certify that the above document was prepared in Microsoft Word using 14-point Times New Roman font.

CERTIFICATE OF SERVICE

I hereby certify that the above document was electronically filed using the CM/ECF system and was served upon counsel of record via electronic mail on this 30th day of December.

/s/ Jack Wenik

Jack Wenik, Esq.
Epstein Becker & Green, P.C.
One Gateway Center, 13th Floor
Newark, New Jersey 07102
(973) 639-5221
jwenik@ebglaw.com
Admitted Pro Hac Vice